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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/548,685	SHEITMAN ET AL.	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2005* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/20/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6197746 (to Beck et al.), in light of the "Repligen Licenses Secretin Diagnostic Products from ChiRhoClin" article, and in view of the Diagnostic and Statistical Manual of mental Disorders, Fourth Edition Text Revision, American Psychiatric Assn. Pub., 2000 (hereafter, DSM-IV-TR), Chapter on "Schizophrenia and Other Psychotic Disorders" (beginning at p. 297).

Beck et al. teach a method of treating schizophrenia, and other neurological disorders, with secretin (see: abstract; col. 7, lines 10-23). The reference particularly discusses the role of CCK (cholecystokinin) to secretin, and how deficiencies of CCK have been linked to schizophrenia (see col. 5 line 64 – col. 6 line 10).

Further, the reference teaches that secretin, in addition to activities on digestive function, "also appears to improve the abnormal brain activity in individuals having symptoms of autism" (col. 5, lines 64-67). The reference goes on to explain the following relationship between secretin and brain activity and behavioral function (col. 6, lines 1-31):

> While causing pancreatic secretions, secretin also stimulates the production of cholecystokinin (CCK). Deficiencies in CCK have been linked to other neurological disorders, such as schizophrenia, and CCK production has been found to be related to levels of the neurotransmitter serotonin. Thus, secretin may be indirectly related to the body's natural production of serotonin. The increase in serotonin levels in the blood after the procedure in EXAMPLE 1 supports this relationship between secretin and serotonin.
>
> Without proper modulation of neurotransmitter levels (i.e., serotonin) in the brain, the brain will not function properly. The inability to modulate neurotransmitter levels has been found to be related to other neurological conditions as well as autism. Thus, a secretin deficiency may cause an imbalance or improper modulation of neurotransmitter levels that results in autistic spectrum disorder or other neurological disorders. Administering secretin to patients with these disorders will modulate the neurotransmitter levels and correct the behavioral symptoms, such as the inability to process language and other maladaptive behavioral patterns. The secretin may also correct abnormalities in immune system functions, as indicated by the reduction of measles, mumps and rubella antibodies in the patient after the secretin administration in EXAMPLE 1. Secretin has also been found to stimulate dopamine production through its precursor, tyrosine hydroxylase. Dopamine levels have been implicated in a variety of mental and behavioral disorders such as Parkinson's and Alzheimer's disease.
>
> A secretin deficiency can therefore account for the gastrointestinal disorders as well as the behavioral symptoms found in many individuals with autistic spectrum disorder.

The reference also teaches the following regarding method of administration, including transdermal (see col. 6, line 48- col. 7 lines 10):

> Although the above examples use Secretin-Ferring, the present invention contemplates other forms of natural or synthetic secretin. The present invention also contemplates using other types of transdermal carrier substances in addition to DMSO. Further, the present invention contemplates other alternative ways of administering secretin including, but not limited to, administering secretin transdermally with a gel, lotion or patch; administering secretin with a suppository; administrating secretin orally, as tablet, capsule or lozenge; administrating secretin by inhalation (e.g., as an acrosol) either through the mouth or the nose. Such alternative methods of administering secretin are less invasive, do not have to be carried out by a doctor at a medical facility, and are less expensive. In addition, the level or dose of administration of secretin can be varied from those examples stated herein including, for example, intravenous administration over a period of time of several hours instead of several minutes and/or a smaller, maintenance or daily dose administered intramuscularly, transdermally or by other methods as disclosed herein or their equivalent.
>
> A further alternative method of transdermally administering secretin includes the use of acoustic waves to permeate the skin. For example, acoustic waves generated using ultrasound or a shockwave from a pulsed laser have been found to make the skin temporarily permeable. A few minutes of low-frequency ultrasound (sound greater in frequency than 20 kilohertz) creates tiny cavities through which the secretin (alone or combined with another transdermal carrier substance) can be diffused.

The reference Example 2 teaches the treatment of a 4 year old patient, wherein the secretin was administered at a dosage of 75 CU (clinical units) over the course of several days at about 15 CU per day (see col. 5 lines 15-25). DMSO was administered to the skin, 4 drops of the secretin were placed onto the DMSO, then it was rubbed it into the skin, thus meeting the particular dosing and administration limitations of claims 2, 5-14, 17, and 20-29.

Regarding limitations to symptoms related to behavioral improvements, the reference teaches a variety of symptoms that improved after secretin infusion (see Table 1 in col. 4): improvement in "spinning episodes" (which are considered a compulsive repetitive behaviors); improved focus (which is considered a thought disorder or disorganized thinking); improved sleeping patterns (which is a decrease in agitation); improved language, and social interactions.

Regarding limitations to the type of secretin (instant claims 3, 4, 18 and 19), the reference uses Secretin-Ferring, which is a natural porcine version of the peptide hormone, extracted from pig intestines (See: article "Repligen Licenses Secretin Diagnostic Products from ChiRhoClin"). As the Beck et al. reference teaches the administration of the Secretin-Ferring type of secretin, this article is only cited to describe the properties of the active agent already taught.

Regarding the course and duration of schizophrenia, the DSM-IV-TR states that some individuals display exacerbation and remission, whereas other remain chronically ill, but due to "variability in definition and ascertainment, an accurate summary of the long-term outcome of schizophrenia is not possible", but "[c]omplete remission (i.e., a return to full premorbid functioning) is probably not common in this disorder." (p. 308-309). Additionally, the patients who remain ill may remain relatively stable presenting with negative symptoms (according to the diagnostic criteria), whereas some get progressively worse, and the positive symptoms emerge (p. 309). Thus, according to the DSM-IV-TR, teaching the refractory nature of schizophrenia and meeting the limitations of claims 15 and 33. As such, it would have been obvious to one of ordinary skill in the art to use secretin to treat refractory schizophrenia, having been taught by the DSM-IV-TR that schizophrenia is refractory in its duration and outcome, motivated by the desire to continue treating the individual in an effort to maintain a stable outcome.

The DSM-IV-TR teaches that the essential features of schizophreniform disorder are "identical to those of schizophrenia" except that the duration of the illness is at least 1 month but less than 6 months, effectively making it a "provisional" diagnosis of schizophrenia (see p. 317). The majority of individuals of individuals diagnosed with schizophreniform disorder receive

schizophrenia or schizoaffective disorder as their final diagnosis (p. 318). As the symptoms of schizophreniform are the same as those for schizophrenia, it would have been obvious to one of ordinary skill in the art to also treat it with secretin as taught by Beck et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use secretin in treating individuals with schizophrenia, schizoaffective disorder, or schizophreniform disorder, having been taught by beck et al. that secretin is effective in treating autism and its behavioral symptoms. Beck et al. clearly suggests that schizophrenia may also be treated with secretin (again see col. 7 lines 16-22). One would be motivated to treat the instantly claimed schizophrenia spectrum of disorders by the desire to modulate the neurotransmitter levels and thereby treat the behavioral symptoms. As Beck et al. have shown that secretin is successful in such a modulation in autistic symptom, there is a reasonable expectation that it would also do in the claimed schizophrenia spectrum of disorders. Further, having been taught by the DSM-IV-TR that the symptoms of schizophrenia, schizoaffective, and schizophreniform disorder are similar, and the patient population have much overlap, one of ordinary skill in the art would have a reasonable expectation that secretin would treat schizoaffective, and schizophreniform disorder as well.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description:

Claim(s) 1, 2, 4-17, and 19-35 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses secretins, such as human secretin, porcine secretin, and bovine secretin which meet the written description and enablement provisions of 35 USC 112, first paragraph. A review of the prior art states the following regarding different species types of secretin (See U.S. Patent No. 4806336 to Mats et al., col. 1, lines 7-25, citation in text omitted):

> Secretin is an intestinal hormone formed by the mucosa of the upper portion of the small intestine, which stimulates the secretion of water and bicarbonate from the pancreas. The structure of porcine secretin has been known for some time and it has been isolated from porcine intestine and has been found to be constituted by a peptide composed of 27 amino acid residues ... Moreover, it has been found that bovine and porcine secretins are identical but that they are markedly different from chicken secretin...Although bovine and porcine secretins behave identically with human secretin in some respects they are not structurally identical.

Claim 1 for example recites secretin generically. Claim(s) 4 and 19 is(are) directed to encompass analogs such as recombinant secretin, synthetic secretin, and natural secretin, which only correspond in some undefined way to specifically instantly disclosed chemicals. Other than human, porcine and bovine "natural secretins" (as described above in the Mats et al. reference), natural secretins (i.e., from other living beings, as well as other analogs of secretins do not meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. While the specification provides a reference to a system for making a fusion protein and a chemically synthesized polypeptide secretin analog (see page 9 of

the specification which refers to the Jaknecht et al. and Creighton references), it provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, *University of California v. Eli Lilly and Co.,* 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement:

Claims 1-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of schizophrenia, schizoaffective, and schizophreniform disorder, does not reasonably provide enablement for prevention of schizophrenia, schizoaffective, and schizophreniform disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of such experiments are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

The nature of the invention & breadth of the claims:

The claims are drawn to methods of treating schizophrenia, schizoaffective, and schizophreniform disorders. The specification defines "treatment" to also include the "prevention" of mental disease as well as "complete and permanent alleviation of symptoms of mental disease" (see p. 5, lines 1-22).

The relative skill of those in the art:

The relative skill of those in the art is high, generally that of an M.D. and/or M.D./Ph.D.

The presence or absence of working examples:

The Example in the specification (pages 17-23) treats subjects diagnosed with schizophrenia or schizoaffective disorder (according to the DSM-IV) by administering the natural porcine (Secretin-Ferring) type of secretin. Patients only received a single infusion and it should be noted that there was no significant difference at week 2, but the difference reappears again at week 3. (See Table 3). Additionally, the Table states that there were "no statistically significant differences between groups on any of the PANSS measurement". This result would suggest that this secretin does not predictably treat many of the problematic symptoms of the schizophrenia and schizoaffective disorder.

The state of the prior art & the predictability/unpredictability of the art:

The state of the prior art regarding the treatment of schizophrenia, schizoaffective, and schizophreniform disorders, is complex as well as unpredictable. The DSM-IV-TR classifies the

disorders according to various combinations of psychotic and mood symptoms (see p. 298, 312). Additionally, the timing and duration with which the different types of symptoms present is also extremely variable among patients, such as the presence of depressive and/or manic moods at the same time, or separate from, a psychotic episode (see p. 298, 312).

The complexity of schizophrenia vs. schizoaffective disorder vs. schizophreniform disorders is addressed in Abrams et al. The article discusses how the conditions are particularly hard to distinguish and they may not be different, but co-occurring conditions with extreme degrees of severity (see: abstract and intro on p. 1089-1090). Abrams et al. also discuss how persons with schizoaffective, as well as schizophrenia and other psychotic mood disorders suffer from other comorbid dysfunctions (such as obsessive compulsive disorder and PTSD), p. 1091-1092. The symptoms of the schizophrenia spectrum disorders "cross conventional categorical boundaries between psychotic disorders and mood disorders" (abstract).

The specification does not enable a person skilled in the art to which is pertains to make or use the invention commensurate in scope with the claims. Applicants have failed to provide guidance and information sufficient to allow the skilled artisan to ascertain that the present active agents (i.e., secretins) are effective against for preventing schizophrenia, schizoaffective, and schizophreniform disorder. The limited enablement for SPECIFIC EXAMPLE is noted but does not support a conclusion that the claimed schizophrenia spectrum disorders can be *prevented* with the claimed active agents. Prevention, and treatment with any type of secretin (such as that from animals other than porcine or human or synthetic type) cannot be accomplished with any reasonable certainty or without undue burden of experimentation.

For inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, as is the case for preventing schizophrenia, schizoaffective, and schizophreniform disorder, more evidence is required to show possession (MPEP § 2163). As discussed above, the DSM-IV-TR states that some individuals display exacerbation and remission, whereas other remain chronically ill, but due to "variability in definition and ascertainment, an accurate summary of the long-term outcome of schizophrenia is not possible", but "[c]omplete remission (i.e., a return to full premorbid functioning) is probably not common in this disorder." (p. 308-309). Additionally, the patients who remain ill may remain relatively stable presenting with negative symptoms (according to the diagnostic criteria), whereas some get progressively worse, and the positive symptoms emerge (p. 309).

Absent a reasonable *a priori* expectation of success for using secretin to treat and *prevent* schizophrenia, schizoaffective, and schizophreniform disorder, the practice of the invention, as it is claimed in its current scope, would require an undue amount of experimentation because the specification provides inadequate guidance to do otherwise.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-14 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how much secretin is administered in a "clinical

unit". The specification at pages 10-11 states that the Secretin-Ferrin (a.k.a. Secreflo) product has a potency of "approximately 5000 clinical units (CU) per milligram of peptide as opposed to 3000 CU per milligram for biologically derived porcine secretin", and that there are 0.2 micrograms of secretin to 1 CU. However, the claims do not specify which type of secretin is used and there is a great difference in potency, such that it is unclear how much secretin is in the claimed dosages.

Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what Applicant means by each of schizophrenia, schizophreniform, and schizoaffective disorder as the specification at p. 4 states the following:

> As used herein, "schizophrenia" refers to a serious, often chronic, mental disorder affecting a variety of aspects of behavior, thinking and emotion and as defined in the DSM-IV, including refractory schizophrenia. As used herein, the term "schizophrenia" is intended to encompass not only the specific disorder defined in the DSM-IV as schizophrenia, but also related mental disorders, including schizoaffective disorder and schizophreniform disorder.

It is not clear what criteria are used to define schizophrenia, schizoaffective, and schizophreniform disorder. Further, while applicant states that the DSM-IV is incorporated by reference, no copy has been provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants provide a list of references beginning at page 25 of the specification, but do not provide copies on a form PTO-1449. The incorporation of **essential material** in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

In this case, Applicant states that the DSM-IV is incorporated by reference (see page 25 of the specification). However no copy has been provided. The DSM-IV is a standard reference those skilled in the art of studying and treating mental disorders use in diagnosing, classifying and differentiating (i.e., defining) the mental disorders in the treatment of patients. The definition of what constitutes schizophrenia, schizoaffective disorder and schizophreniform disorder is essential material to the meaning and scope of the claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Iancu I, et al., "A follow-up study of patients with DSM-IV Schizophreniform disorder," Can J Psychiatry, Vol 47(1), Feb 2002. This article discusses the unclear diagnostic factors (as they overlap with schizophrenia and schizoaffective disorder) as well as the poor prognosis.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is 571-272-9032. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy A. Lewis

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614